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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. FILING DATE 05/28/2002 8437 10/031,851 Horst Rapp HMN 2 0021 02/16/2006 **EXAMINER** 7590 Scott A McCollister CHONG, YONG SOO Fay Sharpe Fagan Minnich & McKee ART UNIT PAPER NUMBER Seventh Floor 1100 Superior Avenue 1617

DATE MAILED: 02/16/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)
Office Action Summary		10/031,851	RAPP ET AL.
		Examiner	Art Unit
		Yong S. Chong	1617
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
2a) <u></u>	Responsive to communication(s) filed on <u>23 January 2006</u> . This action is FINAL . 2b) This action is non-final. Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims			
4) ☐ Claim(s) 1-19 is/are pending in the application. 4a) Of the above claim(s) is/are withdrawn from consideration. 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 1-19 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. 			
Priority u	ınder 35 U.S.C. § 119		
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 			
Attachmen	• •		
2) 🔲 Notic 3) 🔲 Inforr	e of References Cited (PTO-892) e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal Pa 6) Other:	

DETAILED ACTION

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Status of the Application

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/23/2006 has been entered.

Claim 20 has been cancelled. Claims 1-19 are pending and are examined herein.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham vs John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 1-6, 9-13, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wakeman (US Patent 3,317,540) for same reasons of record stated in the Office Action dated November 17, 2004.

Wakeman discloses that tosylchloramide(s) and its known derivatives are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection (see col.1 and col.3 lines 53-56). Wakeman discloses the pharmaceutical compositions of tosylchloramide(s) and their salts in a form, a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion (see col. 2 line 32 to col.3 line 38). Saito et al. discloses that the particular adrenal enzyme inhibitor, trilostane, is useful in the pharmacological treatment of Cushing's syndrome by reducing the steroid production in the patients showing severe hypertension and diabetes mellitus. See title and the English abstract of the Japanese journal article.

Wakeman does not expressly disclose the employment of tosylchloramide(s), in the methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein, because tosylchloramide(s) and their salts are known

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to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to Wakeman. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, the known antiseptics and disinfecting agent would have beneficial therapeutic effects and usefulness in methods of treating instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Thus the claimed invention as a whole is clearly prima facie obvious over the combined teachings of the prior art.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Vandevelde et al (WO 91/07876) for the same reasons of record stated in the Office Action dated November 17, 2004.

Vandevelde et al discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-8 and claims 1-28). Vandevelde et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake

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mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-13 at page 9-20).

Vandevelde et al. does not expressly disclose the employment of tosylchloramide(s), in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Vandevelde et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

Claims 1-19 are rejected under 35 U.S.C. 103(a) a: being unpatentable over Harwardt et al (DE 41 37 544) for the same reasons of record stated in the Office Action dated November 17, 2004.

Harwardt et al discloses that tosylchloramide(s) and its known derivatives, in particular, such as Chloramin T, are useful in a pharmaceutical composition by topical

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administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus (see abstract and page 1-4 and claims 1-7). Harwardt et al. discloses the pharmaceutical compositions of tosylchloramide(s) in various forms herein such as a liquid, solid, water containing preparation, a solution, a shake mixture/dry suspension, or an O/W or W/O-emulsion, and the instant effective amounts of Chloramin T (see Example 1-5 at page 3-4).

Harwardt et al. does not expressly disclose the employment of tosylchloramide(s) in methods of the particular skin diseases herein.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to employ tosylchloramide(s) and their salts in the methods of the particular skin diseases herein.

One having ordinary skill in the art at the time the invention was made would have been motivated to employ tosylchloramide(s) and their salts in methods of the particular skin diseases herein, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases therein such as retrovirus according to Harwardt et al.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, being known in treating skin retrovirus, would have beneficial therapeutic effects and usefulness in methods of treating herpes simplex virus.

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Response to Argument

Applicant argues that the cited references neither disclose nor suggest the use of tosylchloramide compounds in the treatment of the particular skin diseases or even diseases that are remotely similar.

Nevertheless, it must be recognized that any judgment on obviousness takes into account knowledge which was generally available and within the level of ordinary skill at the time the claimed invention was made. In this case, as pointed out in the previous Office Action, because tosylchloramide(s) and their salts are known to be useful in a pharmaceutical composition by topical administration to skin broadly and hair and methods of treating skin diseases by antiseptics, antidandruff, and disinfection according to the cited prior. It is also well-known that the many instant particular skin diseases for examples, psoriasis, aphthae, herpes simplex virus are caused by microorganisms and/or accompanied by microorganisms.

Therefore, one of ordinary skill in the art would have reasonably expected that tosylchloramide(s) and their salts, the known antiseptics and disinfecting agents would have beneficial therapeutic effects and usefulness in methods of treating instant, particular skin diseases for examples, psoriasis, aphthae, herpes simpfex virus, by antiseptic action and disinfecting the affected skin area through killing and destroying microorganisms.

Moreover, a chemical composition and its properties are inseparable. The

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burden is shifted to Applicant to show clear and convincing factual evidence of nonobviousness or unexpected results, i.e., side-by-side comparison with the closest prior art in support of nonobviousness for the instant claimed invention over the prior art. For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejections are adhered to.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHENGJUN WANG PRIMARY EXAMINER

YSC